

REMARKS


It is believed that the claims clearly identify allowable subject matter in the application as recited by the amended claims. If the Examiner believes that negotiations on the scope of allowance of the present claims could advance the present case towards allowance, the Examiner is courteously invited to call the attorney of record, Mark A. Litman, at **952.832.9090** to interview the application. The claims are believed to be in condition for allowance at this time.

Respectfully submitted,
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Date October 2, 2003

By



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with appropriate postage prepaid in an envelope addressed to MAIL STOP: PATENT APPLICATIONS, P.O. BOX 1450, Commissioner for Patents, Alexandria, VA 22313-1450 on October 2, **2003**.

Name Mark A. Litman

Signature



Clean copy of amended paragraphs in the specification and amended or new claims in compliance with 37 C.F.R. 1.121

Amended text on page 1, after the title:

RELATED APPLICATIONS

This Application is a divisional application and claims priority under 35 U.S.C. 120 from U.S. Patent Application Serial No. 09/567,966, filed May 10, 2000, titled APPARATUS AND METHOD OF FLUID INFUSION, now U.S. Patent No. 6,---,---.

Amended page 9, lines 3-4:

Figures 17a) – 17c) show a perspective view of separate components which may be used in an example of a fluid control assembly similar to that shown in Figure 16.

Amended page 12:

As noted earlier, the spacing outside of the area covered by the FCM **14'** access port **24'** and input port **32'** may be unequally distributed. As shown in Figure 10, the areas **41'** and **43'** adjacent to the flush receiving grooves **35'** are not of equal dimensions. Here it is shown (by way of example) that the panel area **41'** is bigger than panel area **43'**. The purpose for this is to enable the placement of additional components underneath the panels **41'** and **43'** with fewer restrictions in size. For example, a much larger (and therefore more likely to be a more longer lived) energy source may be placed under panel **41'** than if panel **41'** were the same size as panel **43'**. Similarly, as motors may be small without sacrificing their ability to perform any necessary functions, they may be located under panel **43'** while preserving the larger space desirable for the energy source and other elements which may be placed under panel area **41'**. As shown in Figure 10, a valve port **124** is shown receiving a rotatable stopper **122** which can be driven by motor (not shown) under panel area **43'** and powered by a battery **45** under panel area **41'**. The motor may cause the rotatable stopper **122** to rotate to open or close the flow or passage of liquids within the access port **34'**. Upon appropriate signaling, as from the information stored on the chip **44'** delivered to the motor.

Amended page 14, line 17 through page 15, line 17:

Referring now to Fig. 6a-6d, the position of the rotors 60, 62 their associated magnets 84, 86, 90, 92, and the control linkage magnets 66, 70 are schematically represented for controlling flow through the FCM 14. Fig. 6a shows the positions of the rotors and magnets corresponding to the rotor configuration of Fig. 5a. The magnet 66 strongly attracts and holds the magnet 84 stationary, locking the rotor 60 against rotation, and correspondingly locking the rotor 62 coupled by the spur gears 94, 96 to the rotor 60. It is to be noted that the fluid from the therapy bag 24 under pressure from the bladder 26 has filled the inlet cavity 100 (Fig. 5a) of the FCM 14. However, flow of the fluid from the inlet cavity 100 is blocked by the stationary rotors 60, 62. Hence, there is no flow of fluid that is contained within the outlet cavity 102 (Figure 5a) of the FCM 14 to the patient through the outlet port 40. For a bolus of medication to flow from the FCM 14, the program of the ECU 22 transmits a "rotate command" to the motor 74 (Figs. 4b and 4c) and the motor 74 rotation shuttles the command linkage 72 to shift the magnet 66 from its position proximate the rotor magnet 84. This frees the rotor 60 from the magnetic force of the magnet 66 and allows it to rotate a quarter turn, while the rotor 62 rotates in the opposite direction. Because of the geometrical configuration of the contours of the rotors 60, 62, the fluid pressure within the inlet cavity 102 applies a greater force perpendicular to the moment arm of the rotor which is in contact with the waist of the other rotor, than the fluid pressure applies to the moment arm of the rotor in contact with the shell 82 of the FCM 14. (The moment arm of rotor 60 in contact with the waist of rotor 62, compared to the moment arm of the rotor 60 in contact with the cavity shell 82, in this example). This difference in force causes the "just released" rotor (rotor 60 in this example), to rotate in a counterclockwise direction, while the rotor 62 rotates in a clockwise direction. In the meantime, the magnet 70 has been positioned by the linkage 72 into the position shown schematically in Fig. 6b, and after a quarter rotation the magnets 84, 86 of rotor 60 and the magnets 92, 90 are positioned as shown, with the magnet 70 attracting and holding the magnet 90. This quarter rotation has forced a bolus of medication previously in the cavity 102 through the outlet port 40 out into the set

connected to the patient. Figs. 6c, 6d illustrate sequences of further quarter turns of the rotors 60, 62 each of which provides one bolus of medication to the patient.

Amended page 19, lines 13-22:

In Fig. 5a, for the rotor positions depicted, the south pole of the control linkage magnet 70, is oriented so that it is in close proximity to the north pole of the magnet 90 embedded in the rotor 62, while the control linkage magnet 66 is horizontally displaced away from the magnetic structures of the FCM 14. The south pole of magnet 70 is strongly attracted to the north pole of the magnet 90, locking the position of the rotor 62 (and simultaneously locking the rotor 60 due to the intermeshing spur gears 94, 96), keeping both of the rotors 60, 62 immobile. With the inlet port 38 of the FCM 14 connected to a fluid filled therapy bag 24 which is under pressure from the bladder 26, for the locked FCM 14 condition described above no fluid, other than a small controlled "non clotting flow" traversing a small intentional gap 94 between the "in contact" contours of the rotors 60, 62, can flow through the FCM 14.

Amended page 22, line 19 through page 23, line 2:

A third embodiment, illustrated in Figs.9-13, discloses the FCM 14' as an integral part of the therapy bag 24'. In the drawings, different but related elements are identified by the same reference character, albeit that the different elements are distinguished by primes. In the earlier embodiment of Fig. 3c, the FCM 14 is not integral with the therapy bag 24, but is a separate unit connected to the therapy bag 24 by the set tubing 16. In the third embodiment, the FCM 14' is included in the output connector 34' of the therapy bag 24' (Figs. 9, 10) and the tubing 42' to the patient connects to the output connector 34' containing the FCM 14'. The therapy bag 24' is filled by means of the input connector 32' and contains an electrical connector 44' connecting with an EPROM (not shown) internal to the therapy bag 24' which performs the same function as the EPROM 46 as previously described above. Associated with the input connector 32' and output connector 34' is a docking element 35 which fits into a mating recess 37' (along with the

input and output connectors 32', 34'), in the pump 12' when the therapy bag 24' is assembled with the pump 12'.

Amended page 23, line 3 through page 24, line 9:

The FCM 141 may be seen by referring to Figs. 11, 12, 13. Part of the FCM 14' is the docking element 35, which is a fiberglass boxlike structure supporting a shaft 118 having bevel gear 120 mounted on one end of the shaft 118, and a magnet 122 mounted on the other end of the shaft 118. The end of the shaft 118 on which the magnet 122 is mounted, fits into a cylindrical cavity 124 in the side of the output connector 34', however fluid from the therapy bag 24' will flow around the outer walls of the cavity 124. Mounted proximate the cavity 124 in the output connector 34' are the other elements of the FCM 14', i.e., a "cork" 126 having one end bulbous shaped and the other end in the shape of a cylindrical rod, and an associated magnet 128 fitted into the bulbous end of the cork 126. Referring to Fig. 10, the docking element 35, when docked to the mating recess 37, causes the bevel gear 120 to engage a spur gear 130 (Fig. 13) attached to shaft of a drive motor 132. In Fig. 13 the small bar magnet 122 is seen mounted on the opposite end the shaft 118 from bevel gear 120, and when the docking element 35 is engaged in the recess 37, the bar magnet 122 is facially juxtaposed opposite the magnet 128 attached to the cork 126. For the rotation position of the bevel gear 120 shown in Fig. 13, the magnets 122, 128 are seen in attractive positions of N versus S respectively, drawing the cork 126 to block the upper portion of the channel of the output connector 34' (Fig. 14a), thereby operating as check valve denying back flow from the set to the therapy bag 24. The motor 132 operates under control of the ECU 22, which controls flow of the fluid by sending a rotate signal to the motor 132. Upon receipt of a rotate signal, the shaft of the motor 132 rotates 180 degrees, and the spur gear 130 drives the bevel gear 120 through 180 degrees, reversing the orientation of the magnet 122. This cause the magnet 122 to repel the magnet 128 of the cork 126, moving the cork 126 downward (as seen in Fig. 14a) from the check valve position, and allowing the flow of the fluid from the therapy bag 24' around the cork 126 as shown by the dotted lines of Fig. 14b. Under the pressure of the fluid flow the cork 126 moves down in the channel of

the output connector 34' until the bulbous portion of the cork 126 snugly mates with the constriction in the channel of the output connector 34' as shown in Fig. 14c. This shuts off the flow from the pump 12', having allowed one bolus of fluid to flow out to the patient. For the next rotation of the bevel gear 120 under control of the motor 132, the magnets 122,128 again attract each other, returning the cork 126 again into the check valve position of Fig. 14a.

Referring again to Fig. 13, a laser led 134 directs a beam of light through transparent walls of the output connector 34' to a photodiode 136. The excitation for the laser led 134, and the output of the photodiode are connected through the electrical connector 44' to the ECU 22. Each time a bolus of medication is transferred out through the output connector 34', the end of the cork 126 interrupts the laser beam and a signal is transmitted to the ECU 22 from photodiode 136. If the ECU signals for a cycle of bolus, and there is no corresponding interrupted light output sensed by photodiode 136 the alarm mode is activated by the ECU 22.